510(k) SUMMARY: BEACON® Stabilization System Additional Implants

Company: Globus Medical Inc.
2560 General Armistead Avenue
Audubon, PA 19403
(610) 930-1800

JUL 26 2012

Contact: Meriam Youssef
Project Manager, Regulatory Affairs

Date Prepared: June 29, 2012

Device Name: BEACON® Stabilization System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
Product Codes: MNH, MNI, KWQ, KWP, NKB

Regulatory Class III, Panel Code: 87

Predicate(s): BEACON® Stabilization System (K073172, K092610 & K100788)
REVERE® 4.5 Stabilization System (K113395)
REVERE® Stabilization System (K061202)
REVOLVE® Stabilization System (K111449)
Synthes® USS (K082572)

Purpose:
The purpose of this submission is to request clearance for specialty rods and HA coated screws as additional implants in the BEACON® Stabilization System.

Device Description:
The BEACON® Stabilization System consists of rods, posted screws, reduction screws, clamps, ML connectors, other connectors and associated manual surgical instruments. Screws and rods are available in a variety of sizes to accommodate individual patient anatomy. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Screws, clamps and rods may be used anteriorly or posteriorly. Connectors are intended for posterior use only. Preassembled clamps are used to connect screws to the rod.

The most common use of this screw and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws. The most common use of this screw and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via screws through an appropriate size staple.

The rods are composed of titanium alloy, commercially pure titanium or cobalt chromium-molybdenum, as specified in ASTM F136, F1295, F67 and F1537. All other BEACON® implants are composed of titanium alloy, as specified in ASTM F136 and F1295. The screws are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy or cobalt chromium-molybdenum alloy implants.

Indications for Use:
The BEACON® Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the BEACON® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system (using REVERE® hooks), the BEACON® Stabilization System is intended for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudoarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the BEACON® Stabilization System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Basis for Substantial Equivalence:
The BEACON® Stabilization System additional implants are similar to the predicate devices with respect to technical characteristics, material, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Globus Medical, Incorporated
% Ms. Meriam Youssef
Project Manager, Regulatory Affairs
2560 General Armistead Avenue
Audobon, Pennsylvania 19403

Re: K121922
Trade/Device Name: BEACON Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: June 29, 2012
Received: July 2, 2012

Dear Ms. Youssef:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

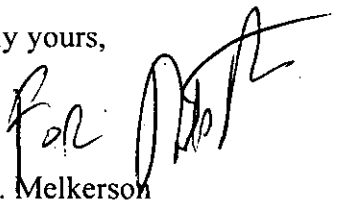
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K121922

Device Name: BEACON® Stabilization System

Indications:
The BEACON® Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

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Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121922

When used as an anterolateral thoracolumbar system, the BEACON® Stabilization System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Prescription Use __X____ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

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